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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/751,587  | 01/05/2004  | David Kanios         | NOPH/108/JGK        | 3003             |
| 7590  | 09/09/2004  |                      | EXAMINER            |                  |
| Noven Pharmaceuticals, Inc.                                     |             |                      | DURAND, PAUL R      |                  |
| Jay G. Kolman, Esq.<br>11960 S.W. 144 Street<br>Miami, FL 33186 |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 3721                |                  |

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/751,587             | KANIOS, DAVID       |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Paul Durand            | 3721                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on \_\_\_\_.  
2a)  This action is **FINAL**.                    2b)  This action is non-final.  
3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 1-8 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-8 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on 05 January 2004 is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date .

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_ .

5)  Notice of Informal Patent Application (PTO-152)

6)  Other: \_\_\_\_ .

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, Line 12, the phrase "wherein the chiral ...nicotine." Appears to be a providing limitation for the transdermal system and not the sealing step.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schroeder (US 6,225,522) in view of Hunt et al (US 5,268,209) and in further view of Benecke et al (US 5,008,110)

In regard to claims 1-5,7 and 8, Schroeder discloses the invention substantially as claimed including providing a translucent composite package comprised of outer layers 4 and 9, inner layers 15 and 16, that can accommodate a transdermal system of

various type drugs (see Fig.1 C4, L40-52 and C5, L24-34). What Schroeder does not disclose is the packaging specifics. However, Hunt teaches that it is old and well known in the art of packaging drugs to provide a package that is comprised of a pouch that resists the loss of chiral drugs with enantiomers in a transdermal system by providing a package that contains a multiple layer pouch that contains an inner barrier layer that can be comprised of an acrylonitrile and methyl acrylate polymer film 40 that is self sealing, adhesive layer 44, and a degradation layer 42 that can be comprised of a polyester layer (see Figs. 4, 5, C1, L47-51 and C5, L20-31) for the purpose of maintaining the effectiveness of the drug. Furthermore, Benecke teaches that is old and well known in the art to have a transdermal system that is comprised of a drug other than nicotine, such as buprenorphine to have a inner layer comprised of acrylonitrile methyl acrylate for the purpose of maintaining the effectiveness of the drug (see Fig.4 and C7,L1-16). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the invention of Schroeder with the film means as taught by Hunt and Benecke for the purpose of maintaining the effectiveness of the drug.

In regard to claim 6, Hunt discloses the invention substantially as claimed except for the specific property of making the package child resistant. However, the examiner takes Official Notice that it is old and well known in the art to provide medical packaging that is child resistant as a means of increasing safety for the user. Therefore, it would have been obvious to one having ordinary skill in the art to have provided the invention of Hunt with child resistant packaging in order to increase safety for the user.

***Conclusion***

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Durand whose telephone number is 703-305-4962. The examiner can normally be reached on 0730-1800, Monday - Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi I Rada can be reached on 703-308-2187. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Durand  
September 2, 2004



EUGENE KIM  
PRIMARY EXAMINER